

REMARKS

The present application is a Continuation Application of U.S. Patent Application No. 09/327,814 filed June 8, 1999. The composition claims of the parent application were canceled during prosecution of the parent application, at which time, the parent application was limited to prosecution of the method claims. The purpose of this Continuation Application is to continue prosecution of the composition claims.

The composition claims were previously rejected under 35 U.S.C. § 102(b) as being anticipated by *Wehling et al.*, U.S. Patent No. 5,178,878. The composition claims were also previously rejected under 35 U.S.C. § 103(a) as being obvious over *Wehling et al.* in view of *Tsuk et al.*, U.S. Patent No. 3,972,995, *Roser et al.*, U.S. Patent No. 5,958,455, *Snipes*, U.S. Patent No. 5,135,752, and *Balkin*, U.S. Patent No. 5,656,284.

The Preliminary Amendment cancels all of the original claims and introduces new composition claims 14-21. Claims 14-21 differ from the original filed composition claims in that they include the limitation that the orally administerable medicament is not substantially encompassed by or dispersed in a material that prevents absorption of the medicament across the oral mucosa. Support for this recitation is found, *inter alia*, in the specification's teaching that the effervescent agent is used to promote absorption of the medicament across the oral mucosa. Thus, by definition, the claims necessarily cannot cover a composition in which the medicament is substantially surrounded by or dispersed in a material that prevents absorption of the medicament across the oral mucosa. No new matter has been added in the Preliminary Amendment and entry of these amendments is therefore respectively requested.

By amending the claims in this manner, claims 14-21 now patentably distinguish over *Wehling* alone or in combination with *Tusk*, *Roser*, *Snipes*, and *Balkin*. In particular, the primary reference *Wehling* teaches compositions and methods for administering said compositions in which the active ingredients are substantially encompassed by or dispersed in a

protective coating or matrix which shields the pharmaceutical ingredient from the environment of the mouth. (See *Wehling* at Col. 1, lns. 25-23.) The protective coating of *Wehling* is intended to prevent dissolution of the active ingredient in the mouth after the dosage form is rapidly disintegrated and before the contents are swallowed. Its object is therefore to prevent exposure and dissolution of the drug in the mouth. Drug has to be in solution for taste to be perceived and *Wehling* is primarily concerned with taste masking.

The claims have been amended to further distinguish the invention over *Wehling* on this point. In particular, the claims now recite that the dosage form has a medicament that is not substantially encompassed by or dispersed in a material that prevents absorption of the active ingredient across the oral mucosa.


The teachings of *Tusk*, *Roser*, *Snipes* and *Balkin* do not cure the deficiencies of *Wehling*. Although these secondary references teach holding the dosage forms identified in these references in the mouth, the secondary references do not provide any motivation for one skilled in the art to modify the compositions of *Wehling*, namely, by removing the protective coating or by replacing the protective coating with a coating that does not prevent exposure of the medicament in the mouth. Moreover, one skilled in the art would not be motivated even to combine the teachings of *Wehling* with the methods of the secondary references since *Wehling* teaches away from the administration of the active ingredient across the oral mucosa by preventing exposure of the active ingredient in the mouth.

In view of the above claim amendments and foregoing remarks, it is believed that this application is now in condition for allowance. Reconsideration is respectfully requested. However, if the Examiner still believes that there are any objections to this application, she is encouraged to telephone the undersigned at (908) 654-5000.

If there are any additional charges in connection with this Preliminary Amendment, the Examiner is authorized to charge Applicants' Deposit Account No. 12-1095.

Respectfully submitted,

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